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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,549	11/21/2001	Gyula Vigh		2580

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,549	GYULA VIGH	
	Examiner	Art Unit	
	Kaj K Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-8 and 10-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8 and 10-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 6-8, 10-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Claims 1, 15, 16, 18-21 and 23-25 were previously rejected as containing new subject matter that was not described in the originally filed disclosure. In particular, the examiner could not find any particular support for the isoelectric substance that has a characteristic size that is larger than the pore size of various ion-permeable barriers (see final rejection of 5-4-2004). Although applicant has canceled this particular claim language the examiner alluded to, it appears the applicant has merely reintroduced a similar unsupported concept elsewhere in the claims. For example, claim 1 has been amended to state that the isoelectric substance has "molecular weights such that the isoelectric substance cannot pass through the ion-permeable barriers". Claims 15, 16, 18-21 and 23-25 add the same or analogous language as well. This new claim language suffers from the same problems as the previous amended language. Namely, there doesn't appear to be any support for this in the originally filed disclosure for

making either the size or the molecular weight of the isoelectric substance such that it cannot move through the ion-permeable barrier.

4. Moreover, these claims still contain the language added on 2-09-2004 that the ion-permeable barriers (using claim 1 as an example) "substantially restrict movement of the isoelectric substance through the ion-permeable barrier". This also was not supported by the originally filed disclosure and has not been deleted from these claims.

5. In addition, with respect to the applicant's new language (using claim 1 as an example) "wherein the pI value of the isoelectric gateway remains substantially constant during the electrophoresis", the examiner cannot find support for this in the originally filed disclosure as well.

Claim Objections

6. Claims 1, 16 and 21 are objected to because of the following informalities: In the amendments to these claims, a comma is missing between "non-ionic membrane" and "isoelectric membranes".

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 7 and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bier et al (USP 4,204,929) in view of Faupel et al (USP 5,082,548). Faupel is being relied on for the first time with this office action.

9. With respect to the claims, they were previously anticipated by the teaching of Bier as set forth in the office action of 9-8-2003. Applicant has amended the claims to specify that the isoelectric substance must be have a molecular weight such that it cannot pass through the ion-permeable barriers. Bier teaches the use of a isoelectric substance known as "Ampholine" and for the purpose of examination, the examiner will presume that this material would not meet the claim requirements. Faupel teaches in an alternate isoelectric focusing apparatus that there are low molecular weight ampholytes like Ampholine as well as high molecular weight ampholytes like Immobiline. Faupel also teaches that both of these materials find utility in the isoelectric focusing art. See col. 4, line 25 through col. 5, line 67. Because the Immobilines are polymerized in such a manner that they are immobile (hence the name of the material), they would appear to have a molecular weight that would prevent them from moving through any ion permeable barriers. See col. 4, lines 55-69. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Faupel for the isoelectric gateway of Bier because the substitution of one known and commercially available isoelectric substance for another known and commercially available isoelectric substance requires only routine skill in the art. Furthermore, Faupel also teaches that Ampholine can be polymerized to form an immobilized pH gradient as well. See col. 4, lines 3-24.

10. With respect to the new limitation requiring the pI value of the isoelectric gateway remain substantially constant, absent an explicit definition of what "substantially constant" means and an explicit framing what electrophoretic conditions define the set forth "substantially constant", any of the channels of Bier shown in Table I would meet the claimed requirement. In

particular, the pH of the various channels after 15 minutes remains substantially constant, giving the claim language its broadest reasonable interpretation.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 and Faupel in view of Perry et al (USP 5,087,338).

12. The references set forth all the limitations of the claim, but did not explicitly recite the use of the set forth groups. Perry teaches in an alternate electrophoresis apparatus that suitable membranes can be constructed from cellulose esters and polysulfones (col. 7, lines 60-65). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Perry for the apparatus of Bier and Faupel because the substitution of one known membrane material for another requires only routine skill in the art.

13. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 and Faupel in view of Dubrow (USP 5,164,055).

14. The references set forth all the limitations of the claim, but did not explicitly recite the use of a frit for forming ion-permeable barriers. Dubrow teaches in an alternate isoelectric focusing apparatus that glass frits are a known material for controlling fluid movement across a barrier (col. 4, lines 3-5 and col. 10, lines 52-62). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Dubrow for the apparatus of Bier and Faupel because frits are a known barrier material and the substitution of one known barrier material for another requires only routine skill in the art.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier and Faupel as applied to claim 1 above, and further in view of Martin et al (USP 4,243,507).

16. Bier and Faupel set forth all the limitations of the claim, but did not explicitly recite the use of an isoelectric substance that is a combination of a weak acid and strong base (or strong acid and weak base). Martin also discloses in an alternate isoelectric device that the most convenient means for achieving various pHs for each isoelectric compartment is to utilized a combination of a weak acid and strong base (or a strong acid and weak base) (col. 4, lines 15-29). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Martin for the apparatus of Bier and Faupel because the set forth acid and base combinations are the most convenient means for achieving selective pHs for isoelectric compartments.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bier '929 and Faupel in view of WO 92/15,870 (hereafter "WO '870").

18. The references set forth all the limitations of the claim but did not explicitly recite the use of an isoelectric substance from the claimed group. However, WO '870 teaches that polyamino-polycarboxylic acid is a conventional material utilized for forming an isoelectric substance (p. 2, line 25 through p. 3, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '870 for the apparatus of Bier and Faupel because the substitution of one known isoelectric substance for another requires only routine skill in the art.

Response to Arguments

19. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
January 12, 2005

KAJ K. OLSEN
PRIMARY EXAMINER